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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

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EXAMINER	
HINES, JANA A	
ART UNIT	PAPER NUMBER
1645	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,446	PRICE ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *04 April 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed April 4, 2002 has been entered. Claims 1-22 and 26 have been deleted, however it should be noted that there is no claim 23. New claims 27-60 have been newly added, however applicant is reminded that they incorrectly numbered and should be corrected by applicant. As pursuant to Rule 126, the claims 27-60 have been renumbered as claims 23-56, as are referred to as such in the office action. Therefore, claims 23-56 are under consideration in this Office Action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments:

a) The rejection of claims 1, 7, 9-12, 14-15, 18 and 20 under 35 U.S.C. 102(b) as being anticipated by Beggs et al. (WO 95/01155);

b) The rejection of claims 1, 7, 14-15, 17-20 and 22 under 35 U.S.C. 102(b) as being anticipated by Hirao et al., (EP 278,422);

c) The rejection of claims 2-4, 8, 15-17, 19-20, 22 and 26 under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (WO 95/01155) in view of Friesen (CA 1,168,152);

d) The rejection of claims 5-7 under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (WO 95/01155) in view of Moore et al.;

e) The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Beggs et al. (WO 95/01155) in view of Jansen et al., (EP 318,081);

f) The rejection of claims 1-23 and 26 under 35 U.S.C. 112, second paragraph; and

g) The rejection of claims 18-19 under 35 U.S.C. 101.

New Grounds For Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 23-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising steps for increasing the serum half-life of an immune globulin such as: making an immune globulin preparation with the recited components i.e., non-ionic surface active agents in a formulation to prolong the half-life of the immune globulin; administering parenterally the preparation to an animal in need thereof an immune globulin preparation; and using the pharmacokinetics methods wherein regression was performed on log transformed corrected serum levels against time to determine whether there was an increase in the estimated half-life of the drug in subjects, does not reasonably provide enablement for a method of increasing the serum half-life of an immune globulin comprising parenterally administering to an animal in need thereof an immune globulin preparation or the use of

two or more non-ionic surface active agents in said preparation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims recite a method of increasing the serum half-life of an immune globulin comprising parenterally administering to an animal in need thereof an immune globulin preparation. However, the claims recite that merely administering the preparation will increase the serum half-life, since "administering" is the only active step in the claims. The specification teaches: immune globulin preparation including non-ionic surface active agents; therapeutic dosage of the immune globulin preparation; parenteral administration of the preparation; and using the pharmacokinetics methods wherein regression were performed on log transformed corrected serum levels against time to determine the estimated half-life of the drug in subjects, see pages 19-25 of the instant specification. The specification teaches that the entire method may result in increasing the serum half-life and are necessary to achieve the claimed results, not just administering the preparation. The specification does not teach examples of said method using two or more non-ionic surface agents. Thus, simply mentioning the use of two or more agents in the claims does not provide enablement for a method that has no recited steps; neither does the recitation provided guidance on what combinations of agents can or cannot be used together and how many agents are useable in the preparation. The specification does not teach how to achieve the increased serum half-life merely by administering the preparation at all, nor does the specification teach the

use of multiple surface-active agents in a preparation. Thus, the method recited in the claims does not teach the inclusion of the other necessary steps and the claims are rejected.

4. Claims 40-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 40-56 recite a method of reducing the elevation of neutrophil counts comprising parenterally administering to an animal in need thereof an immune globulin preparation. However, the claims recite that merely administering the preparation will reduce the elevation of neutrophil counts, since "administering" is the only active step. In particular, claim 52 us drawn to a method using two or more non-ionic surface-active agents.

The specification, at page 28 lines 7-10 states that inclusion of Polysorbate 80 in the anti-Rh_oD immune globulin preparation significantly minimized drug-induced elevations of neutrophil counts in the recipients. The specification does not appear to teach that simply administering the preparation will reduce the elevation of neutrophil counts, nor does the specification teach that administration of the preparation will reduce the elevation of neutrophils, induced by some other means; but rather that the preparation itself may reduce drug induced elevations. Furthermore, the specification does not specifically states how the reduction or previous elevation of the neutrophils is being monitored. The specification fails to teach examples of reducing the elevated

neutrophil counts. The specification fails to teach using two or more non-ionic surface-active agents in the method of reducing the elevated neutrophil count. Therefore, the specification fails to enable to a method of reducing the elevation of neutrophil counts.

Applicants have provided no guidance to enable one of ordinary skill in the art how to use, without undue experimentation, the method of reducing the elevation of neutrophils without appropriate positively recited steps. Moreover, there are no examples of said method using two or more non-ionic surface agents. Thus, simply mentioning the use of two or more agents in the claims does not enabled a method that has no recited steps; neither does the recitation provided guidance on what combinations of agents can or cannot be used together. Given the lack of guidance contained in the specification and the unpredictability for reducing elevated neutrophils, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Furthermore, the specification fails to provide an enabling disclosure for the use of any immune globulin besides anti-Rh_oD, that meet the limitations recited in the claims. Applicants' have provided no guidance to enable one of ordinary skill in the art as to how determine, without undue experimentation, other immune globulins that reduce the elevation of neutrophil counts. There is no requirement or limitation for the use of only the anti-Rh_oD immune globulin. Given the lack of guidance contained in the specification and the unpredictability for a method of reducing the elevation of neutrophil counts, one skilled in the art could not make or use the broadly claimed invention without undue experimentation.

5. Claims 40-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have added new claims 40-56 with a preamble drawn to a method for reducing the elevation of neutrophil counts comprising parenterally administering to an animal in need thereof an immune globulin preparation. Applicants point to support in original claims 2-14, 16-17 and 21-22,however it appears that the amendment lacks support. There is no teaching of a method for reducing the elevation of neutrophil counts comprising parenterally administering to an animal in need thereof an immune globulin preparation. The original claims of 2-14 and 16-17 are drawn to a composition, not a method for reducing the elevation of neutrophils. Claim 21 is drawn to a method for reducing the elevation of neutrophils, however the method does not require parenteral administration. Moreover, the specification fails to recite method steps for this method, regarding the type of immune globulin, the purity and weight percent of the immune globulin, or the non-ionic surface-active agents. There is no teaching of the claimed method or method steps that reduce the elevation of neutrophil counts using two or more non-ionic surface-active agents. Applicants have not pointed to support for a method of reducing the elevation of neutrophil counts by page and line number. Therefore, the claims are rejected for incorporating new matter.

6. Claims 23-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "increase the serum life in the claims is a relative term which renders the claim indefinite. The term "increase the serum life" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Furthermore, it is unclear how to define "increase the serum life." Neither the specification nor the claims define what level of increase is required. Further, it is unclear what the increase in serum life is being compared to in order to determine whether there has been an increase. It is unclear if the increase is compared to immune globulin without a nonionic surfactant or compared to a specific nonionic surfactant. Therefore, the metes and bounds of the claim cannot be determined.

7. Claims 23 and 40 recite administering to an animal "in need thereof". It is unclear what the animal is in need thereof. Is the animal in need of the recited methods, the immune globulin preparation or something else? The claim is unclear with respect to how to determine whether an animal is in need thereof an immune globulin preparation. Thus, the claim is unclear.

8. Claims 40-56 The term "to reduce the elevation of neutrophil counts" in claims is a relative term which renders the claim indefinite. The term "to reduce the elevation of neutrophil counts" is not defined by the claim, the specification does not provide a

standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. There is no definition of the initial elevation or of the reduction. Furthermore, the claims are vague and indefinite. It is unclear how to define "to reduce the elevation of neutrophil counts." The phrase is vague and indefinite because it is unclear how to define a reduction of elevation of neutrophils. How much reduction in the elevation is required? How much elevation is required? What is the source of the elevation? Neither the specification nor the claims define how much of a reduction in elevation is needed. Therefore, the metes and bounds of the claim cannot be determined.

9. Claims 24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Abbreviations like anti-Rh_oD and anti-c must be spelled out and defined when used for the first time in a chain of claims.

10. Claims 26, 29, 38,43 and 46 are drawn to a method according to the respective claim which is aqueous and are vague and unclear. It is unclear, how the method is aqueous. Thus appropriate clarification is requested.

11. Claims 38 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods

associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular material, i.e., POLYSORBATE 80 ™, the identification is indefinite. Furthermore, the use of trademarks is improper since products identified by trademarks are within the sole control of the trademark owner and are subject to change by said owner at their discretion.

The terms "very low " level buffer with "essentially no ionic strength" in claims 38 and 55 are relative terms which renders the claim indefinite. The terms "very low" and "essentially no ionic strength" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Thus the metes and bounds of the scope cannot be ascertained.

12. Claims 39 and 56 are unclear. The claims recite a method wherein one or more non-ionic surface agents are selected from the group consisting of glyceryl monooleate. However there is only one reagent to select from. Furthermore, based upon the long list of non-ionic surface-active agent provided by the specification, glyceryl monooleate does not appear to quality as a nonionic surface-active agent. Therefore the claim is unclear and appropriate clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 23, 26, 31-34, 36-37, 40,43, 47,49—51 and 53-54 rejected under 35 U.S.C. 102(b) as being anticipated by Alberici et al., WO 94/16728. Alberici et al., (WO 94/16728, see also the translation in US Patent 6,214,342) teach a composition comprising at least a monoclonal antibody in an isotonic aqueous solution for perfusion and at least one stabilizing agent and TWEEN 80 ™. The solution may comprise from 0.1 to 10 g of monoclonal antibody, 0.1 to 10g of tris (hydrooxymethyl)aminomethane or analogue and particularly 2 per 10 thousand TWEEN 80 ™. The US Patent 6,214,342 equivalent teaches intravenous administration (col. 6 line 21). It is well known that TWEEN 80 ™ is also known as POLYSORBATE 80™.

Thus Alberici et al., teach administering to an animal an immune globulin preparation comprising an immune globulin and at least one non-ionic surface-active agent, TWEEN 80 ™ which is in a concentration sufficient to increase the serum half-life.

It should be noted that, the recitation of a method of increasing the serum half-life of an immune globulin and a method of reducing the elevation of neutrophil counts, has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481

(CCPA 1951). Both of the claimed methods only positively recite administration of the preparation; therefore Alberici et al., meets the claimed limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 23-34, 36-38, 40-51 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen (CA 1,168,152) in view of de Burgh Bradley et al., (1,303,533). Friesen (CA 1,168,152) teaches manufacturing of human plasma fractions contained immune globulin (IgG) where in such fractions may be obtained in concentrated aqueous solution and are useful for intravenous injection (page 1 lines 1-5). The IgG preparation is suitable for intravenous use that is in the form of a dilute aqueous solution (page 1 lines 19-22). The dilute solution containing the IgG is treated with a mixture of sodium chloride and glycine and the dilute solution thus obtained is subject to ultrafiltration to provide a concentrated solution containing IgG. The concentration of the glycine is 0.1M and the sodium chloride is 0.15M (page 3 lines 23-27). The process is suitable for preparing Rh immune globulin for the prevention of Rh isoimmunization by passive administration of anti-D (page 1 lines 18-21). Intravenous injection results in a much more rapid appearance of the Rh antibody in the circulation as well as a higher maximum level and such injection cause less discomfort then the

intramuscular route (page 2 lines 1-4). The purity, anticomplementary activity, safety and other test results were determined according to established procedures before the product (WINRHO) was used in clinical trials and in IgG subclasses anti-C (page 4 lines 24-30). The WinRho product is also known as the anti-Rh_oD immune globulin. The purity and recovery of IgG depends upon the ionic strength and pH of eluting buffer, wherein high-purity occur (page 9 lines 7-13). The ultrafiltration process concentrates the dilute solution from about 1/10 to about 1-100 of the volume of said dilute solution. However, Friesen does not teach the use of the recited non-ionic surface-active agents.

de Burgh Bradley et al., herein referred to as Bradley et al., teach the use of human monoclonal anti-Rh (D) to prevent hemolytic disease in infants. IgG1 antibody wherein the antibody is diluted to include physiological saline or phosphate buffered saline, advantageously containing a surfactant or suspending agent such as TWEEN 80 [polyoxyethylene sorbitan monooleate] (page 14 lines 20-30). The solution for manual use includes sodium chloride, distilled water, and TWEEN 20 [polyoxyethylene sorbitan monolaurate] (page 29 lines 10-17). It is well known that TWEEN 80 ^{TM} is also known as POLYSORBATE 80^{TM} and

It should be noted that, the recitation of a method of increasing the serum half-life of an immune globulin and a method of reducing the elevation of neutrophil counts, has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process

steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify either the method of increasing serum half-life or method of reducing the elevation of neutrophils by intravenously administering an immune globulin preparation comprising at least an immune globulin, sodium chloride and glycine as taught by Friesen in view of Bradley et al., who teaches parenterally administering the same immune globulin preparations comprising several of the same reagents, yet advantageously further comprising a non-ionic surface active agent such as TWEEN 20™ or TWEEN 80™. One would have a reasonable expectation of success in modifying the immune globulin preparation since the prior art already teaches preparations comprising non-ionic surface active agents as being advantageous in immune globulin preparation. Furthermore, no more then routine skill would have been required to incorporate well-known and commercially available reagents such as TWEEN 80™ also known as POLYSORBATE 80™ which immune preparation when the art already teaches their inclusion.

15. Claims 39 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friesen (CA 1,168,152) and de Burgh Bradley et al., (1,303,533) as applied to claims 23 and 40 above, and further in view of Eibl et al., (US Patent 4,276,283). Friesen (CA 1,168,152) and de Burgh Bradley et al., (1,303,533) have been discussed

above, however neither teach the use of polyvinyl alcohol. Eibl et al., teach use methods for preparing an intravenously administrable immune globulin preparation containing antibodies. The preparation can further include water soluble polymers such as polyvinyl alcohol because as soon as the purification of the immune globulin has been effected, the immune globulins can be recovered from solution with water-soluble polymers (col. 3 lines 40-45).

Therefore, it would have been prima facie obvious at the time of applicants invention to modify either the method of increasing serum half-life or method of reducing the elevation of neutrophils by intravenously administering an immune globulin preparation comprising at least an immune globulin and a non-ionic surface active agent taught by Friesen and Bradley et al., wherein the modification further includes the use of polyvinyl alcohol. One would have a reasonable expectation of success in modifying the immune globulin preparation to include polyvinyl alcohol since the prior art already teaches preparations comprising polyvinyl alcohol had aided in the purification process in immune globulin preparation. Furthermore, no more then routine skill would have been required to incorporate well-known and commercially available reagents in the immune preparation when the art already teaches their inclusion.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

July 17, 2002

MARK NAVARRO
PRIMARY EXAMINER